The public record for this rulemaking is available for inspection in the TSCA Nonconfidential Information Center (also known as the TSCA Public Docket Office), Rm. NE B607, 401 M St., SW., Washington, DC from 12 noon to 4:00 p.m., Monday through Friday, except legal holidays.

V. Regulatory Assessment Requirements

A. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether the regulatory action is ''significant'' and therefore subject to all the requirements of the Executive Order (i.e., Regulatory Impact Analysis and review by the Office of Management and Budget (OMB)). Under section 3(f), the order defines ''significant'' as those actions likely to lead to a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (aka ''economically significant''); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlements, grants, user fees, or loan programs; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order. Pursuant to the terms of this order, EPA has determined that this rule would not be ''significant''.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., EPA is certifying that revocation of this test rule will not have a significant impact on a substantial number of small businesses because only the 24 manufacturers who signed the ECAs, which will replace the revoked test rule, will be responsible for conducting and paying for the testing. None of these manufacturers are small businesses.

C. Paperwork Reduction Act

There are no information collection requirements associated with this revocation covered under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq.

List of Subjects in 40 CFR Part 799

Chemicals, Chemical export, Environmental protection, Hazardous substances, Health effects, Laboratories, Reporting and recordkeeping requirements, Testing.

Dated: January 10, 1995.

Lynn R. Goldman,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

Therefore, 40 CFR, chapter I, subchapter R, part 799 is amended as follows:

PART 799—[AMENDED]

1. The authority citation for part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

§799.5050—[Removed]

2. By removing §799.5050.

[FR Doc. 95–1673 Filed 1–20–95; 8:45 am]

BILLING CODE 6560–50–F

40 CFR Part 799

[OPPTS–42134G; FRL–4924–8]

RIN 2070–2033

Testing Consent Orders for Acetone, n-Amyl Acetate, n-Butyl Acetate, Ethyl Acetate, Isobutyl Alcohol, Methyl Isobutyl Ketone, and Tetrahydrofuran

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final Testing Consent Agreements and Orders.

SUMMARY: EPA has issued Testing Consent Orders (Orders) that incorporate Enforceable Consent Agreements (ECAs) pursuant to the Toxic Substances Control Act (TSCA) with companies who have agreed to perform certain neurotoxicity tests with the following seven substances: acetone (CAS No. 67–64–1), *n*-amyl acetate (CAS No. 628–63–7), *n*-butyl acetate (CAS No. 123–86–4), ethyl acetate (CAS No. 141–78–6), isobutyl alcohol (CAS No. 78–83–1), methyl isobutyl ketone (CAS No. 108–10–1), and tetrahydrofuran (CAS No. 109–99–9). This document summarizes the requirements of the ECAs and amends 40 CFR 799.5000 by adding these seven substances to the list of chemical substances and mixtures subject to ECAs. Accordingly, the export notification requirements of 40 CFR part 707 apply to these substances.

EFFECTIVE DATE: January 23, 1995.

ADDRESSES: A public version of the administrative record supporting this action, with any confidential business information deleted, is available for inspection at the TSCA Nonconfidential Information Center, also referred to as the TSCA Public Docket Office (7407), Rm. NE B607, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460 from 12 noon to 4:00 p.m. Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Susan Hazen, Environmental Assistance Division, Office of Pollution Prevention and Toxics, 401 M St., SW., (7408), Washington, DC 20460, (202) 554–1404, TDD (202) 554–0551.

SUPPLEMENTARY INFORMATION: Twelve companies that include AlliedSignal, Inc., Aristech Chemical Corp., BTL Specialty Resins Corp., The Dow Chemical Co., Eastman Chemical Co., Exxon Chemical Co., General Electric Co., Georgia Gulf Corp., Goodyear Tire & Rubber Co., Shell Oil Co., Texaco Refining & Marketing, Inc., and Union Carbide Corp. have agreed to perform neurotoxicity testing with acetone. The Union Carbide Corp. has agreed to perform neurotoxicity testing with *n*-amyl acetate. Nine companies that include Aristech Chemical Corp., BASF Corp., BP Chemicals Inc., Eastman Chemical Co., Hoechst Celanese Chemical Group, Inc., Rhone-Poulenc Inc., Shell Oil Co., Union Carbide Corp., and Vista Chemical Co. have agreed to perform neurotoxicity testing with butyl acetate. Six companies that include BP Chemicals Inc., Eastman Chemical Co., Hoechst Celanese Chemical Group, Inc., Monsanto Co., Rhone-Poulenc Inc., and Tolson USA, Inc. have agreed to perform neurotoxicity testing with ethyl acetate. Five companies that include BASF Corp., Eastman Chemical Co., Hoechst Celanese Chemical Group, Inc., Shell Oil Co., and Union Carbide Corp. have agreed to perform neurotoxicity testing with isobutyl alcohol. Six companies that include Eastman Chemical Co., Exxon Chemical Co., Hoechst Celanese Chemical Group, Inc., Rhone-Poulenc Inc., Shell Oil Co., and Union Carbide Corp. have agreed to perform neurotoxicity testing with methyl isobutyl ketone. Six companies that include Arco Chemical Co., BASF Corp., E.I. duPont de Nemours and Co., GE Plastics, ISP Management Company, Inc., and QO Chemical Inc. have agreed to perform neurotoxicity testing with tetrahydrofuran.

I. Background

On March 4, 1991 (56 FR 9105), EPA proposed neurotoxicity testing of 10 substances under section 4 of TSCA. All 10 substances have wide use as solvents (Refs. 10 and 11). A TSCA section 4(a)(1)(B) finding for substantial exposure was made for each substance based on production volume, occupational and consumer exposure,

environmental release, and volatility (Refs. 10–16).

On July 27, 1993, EPA issued a Final Rule (58 FR 40262) requiring the same neurotoxicity testing of the 10 substances that had been proposed. These tests consisted of the Functional Observational Battery (acute and subchronic), Motor Activity (acute and subchronic), Neuropathology (subchronic), and the Schedule-controlled Operant Behavior test (subchronic). The rule responded to comments on the proposed test rule, discussed EPA's TSCA section 4(a) findings, and specified test standards and reporting requirements.

On October 8, 1993, the manufacturers of the 10 substances petitioned for review of the final rule under TSCA section 19 in the Fifth Circuit Court of Appeals (Ref. 1). Subsequent to the filing of this challenge to the rule, EPA, the Chemical Manufacturers Association (''CMA''), and representatives of the parties challenging the rule, entered into settlement negotiations to resolve the lawsuit.

As a result of these settlement discussions, CMA and the other parties to the lawsuit have agreed, subject to certain conditions set forth in the settlement agreement (Ref. 2), to conduct neurotoxicity and pharmacokinetics testing of seven of the original 10 substances under negotiated ECAs, to be implemented by an order issued by EPA under TSCA section 4. Testing on two of the substances subject to the final rule, *n*- butyl acetate and isobutyl alcohol, is already underway.

On June 27, 1994, EPA issued a stay (59 FR 33184) and a proposed revocation (59 FR 33187) of the final multi-substance rule for the testing of neurotoxicity. Comments on the proposed revocation of the final test rule are addressed in the notice to revoke this rule, published elsewhere in this **Federal Register**.

II. Enforceable Consent Agreement Negotiations

Pursuant to EPA regulations, 40 CFR 790 subpart B, EPA published a **Federal Register** notice (59 FR 33191, June 27, 1994) announcing an opportunity for interested parties to participate in or monitor negotiations for the development of consent agreements for the neurotoxicity testing of the seven substances. It was also announced that the testing agreed to in the settlement agreement (Ref. 2) would be the starting point for the negotiations.

EPA met with identified interested parties, on July 28, 1994, to initiate the negotiation of ECAs (Ref. 17). No new interested parties identified themselves to EPA during the 30–day comment period or during the meeting. The testing program outlined in the settlement agreement was proposed as the basis for the ECAs. Tentative schedules for completing the negotiation and signing the ECAs were discussed. EPA announced that it would take comments from the interested parties on the ECAs. The interested parties submitted comments and raised several issues that required subsequent discussion. The discussions, which were completed in early October 1994, addressed the 8(e) reportability of effects seen above the limit dose and effects seen in the schedule-controlled operant behavior tests, the description of EPA's lead role in arranging a workshop on the test results, a request for assurance from EPA that additional neurotoxicity testing of MIBK would not be required by the Hazardous Air Pollutants (HAPs) test rules currently under development, and that EPA's disclosure of test results be governed by TSCA section 14 instead of limiting disclosures to TSCA section 14(b). EPA agreed to provide the requested assurance in the ECA for MIBK concerning neurotoxicity testing of MIBK under the HAPs rule. EPA also agreed to allow section 14 of TSCA to govern disclosure of test results.

EPA's request to add a list of specific graphs to the data reporting requirements in the SCOB guideline (Ref. 18) was rejected, but the test laboratories were represented by CMA as intending to try to provide the results in the requested format. Requests to change the boilerplate language of the consent agreements concerning EPA's right to assess penalties and to use its professional judgement to determine the scientific adequacy and validity of the test results were rejected.

EPA agreed to the following modifications to the testing program or standards outlined in the settlement agreement: (1) renaming of the ''pharmacokinetics/metabolism'' test of butyl acetate to the ''*in vivo* hydrolysis'' test of butyl acetate; (2) changing the deadline for the submission of the *in vivo* hydrolysis test from 30 months to 24 months; (3) allowing laboratory safety conditions to influence the setting of the high dose at 50 percent of the lower explosive limit for all tests; and (4) not requiring positive control data to be generated once every year during the course of testing if laboratory conditions do not change. The modifications were incorporated in the ECAs which EPA provided to CMA for distribution to the companies for signature.

The companies signed the ECAs in November 1994, and the Assistant Administrator for EPA'S Office of Prevention, Pesticides, and Toxic Substances signed the ECAs and accompanying Orders in January 1995 (Refs. 3 through 9). These ECAs and Orders are final actions by EPA on these seven substances.

III. Testing Program

Table 1 lists the tests, test standards, and reporting requirements for the seven substances under the ECAs and Orders. This testing program will allow EPA to further evaluate the potential neurotoxicity resulting from exposure to these substances.

TABLE 1.—REQUIRED TESTING, TEST STANDARDS AND REPORTING REQUIREMENTS

Substance	Test	Deadline for Final Report[1]	Interim Reports Required[2]
acetone	Scheduled-Controlled Operant Behavior, Subchronic[3]	30	4
n-amyl acetate	Acute Neurotoxicity		
	Functional Observational Battery	24	3
	Motor Activity	24	3
	Subchronic Neurotoxicity[4]		
	Functional Observational Battery	36	5
	Motor Activity	36	5

TABLE 1.—REQUIRED TESTING, TEST STANDARDS AND REPORTING REQUIREMENTS—Continued

Substance	Test	Deadline for Final Report[1]	Interim Reports Required[2]
	Neuropathology	36	5
n-butyl acetate	Acute Neurotoxicity[4]		
	Functional Observational Battery	12	1
	Motor Activity	12	1
	Subchronic Neurotoxicity[4]		
	Functional Observational Battery	24	3
	Motor Activity	24	3
	Neuropathology	24	3
	Scheduled-Controlled Operant Behavior, Subchronic[3]	24	3
	In Vivo hydrolysis[5]	24	3
ethyl acetate	Acute Neurotoxicity[4]		
	Functional Observational Battery	18	2
	Motor Activity	18	2
	Subchronic Neurotoxicity[4]		
	Functional Observational Battery	30	4
	Motor Activity	30	4
	Neuropathology	30	4
	Scheduled-Controlled Operant Behavior, Subchronic[3]	30	4
isobutyl alcohol	Acute Neurotoxicity[4]		
	Functional Observational Battery	12	1
	Motor Activity	12	1
	Subchronic Neurotoxicity4		
	Functional Observational Battery	24	3
	Motor Activity	24	3
	Neuropathology	24	3
	Scheduled-Controlled Operant Behavior, Subchronic[3]	24	3
methyl isobutyl ketone	Scheduled-Controlled Operant Behavior, Subchronic[3]	30	4
tetrahydrofuran	Acute Neurotoxicity[6]		
	Functional Observational Battery	24	3
	Motor Activity	24	3
	Subchronic Neurotoxicity[4]		
	Functional Observational Battery	36	5
	Motor Activity	36	5
	Neuropathology	36	5

[1]Number of months after effective date of the ECA when the final report will be submitted to EPA.

[2]Number of interim reports to be submitted to EPA. Interim reports will be due every 6 months from the effective date until the final report is submitted.

[3]The subchronic schedule-controlled operant behavior (SCOB) test shall be conducted in accordance with the 1991 EPA Guideline for Schedule-controlled Operant Behavior (EPA 540/09–01–123, NTIS No.: PB 154617) as modified.

[4] Acute and subchronic neurotoxicity studies shall be conducted in accordance with the 1991 EPA Guidelines in EPA 540/09–01–123, NTIS No.: PB 154617, pages 13–27 as modified for purposes of these enforceable consent agreements.

[5]The *in vivo* hydrolysis test shall be conducted in accordance with the ''Protocol for Determining the *In Vivo* Hydrolysis of *N*- Butyl Acetate in Rats After Intravenous Administration'' (Ref. 5).

[6] Acute and subchronic neurotoxicity studies shall be conducted in accordance with the 1991 EPA Guidelines in EPA 540/09–01–123, NTIS No.: PB 154617, pages 13–27 as modified for purposes of these enforceable consent agreements.

IV. Test Substances

With the exception of *n*-amyl acetate, the purity of the test substances shall be 99 percent or greater. In the case of *n*-amyl acetate, the test sponsor will be required to select and test a technical grade containing a representative percent of *n*-amyl acetate. The test sponsor will indicate the percent of *n*-amyl acetate in the test substance in the test protocol.

V. Export Notification

The issuance of the ECAs and Orders subjects any persons who export or intend to export any of the seven chemical substances, of any purity, to the export notification requirements of section 12(b) of TSCA. The listing of the chemical substance at 40 CFR 799.5000 serves as a notification to persons who export or intend to export a chemical substance or mixture that is the subject of an ECA and Order that 40 CFR part 707 applies.

VI. Public Record

EPA has established a record for these ECAs and Orders under docket number OPPTS–42134G. This record contains the following information:

A. Supporting Documentation

(1) **Federal Register** notices pertaining to this document, ECAs, and Orders consisting of:

(a) Notice of Proposed Multi-substance Rule for the Testing of Neurotoxicity (56 FR 9105, March 4, 1991).

(b) Notice of Final Multi-substance Rule for the Testing of Neurotoxicity (58 FR 40262, July 27, 1993).

(c) Notice announcing Administrative Stay of Final Multi-substance Rule for the Testing of Neurotoxicity (59 FR 33184, June 27, 1994).

(d) Notice of Proposed Revocation of Final Multi-substance Rule for the Testing of Neurotoxicity (59 FR 33187, June 27, 1994).

(e) Notice announcing Opportunity to Participate in Negotiations for Neurotoxicity Testing; Solicitation for Interested Parties (59 FR 33191, June 27, 1994).

(2) Communications consisting of:

(a) Written Letters.

(b) Contact reports of telephone summaries.

(c) Meeting summaries (including public meeting on July 28, 1994).

(3) Reports - published and unpublished factual materials.

B. References

(1) Chemical Manufacturers Association (CMA). Petition for Review. Filed with United States Court of Appeals for the Fifth Circuit. (October 8, 1993).

(2) United States Court of Appeals for the Fifth Circuit. Settlement Agreement between Environmental Protection Agency (USEPA) and petitioners. No. 93–5381. (April 28, 1994).

(3) United States Environmental Protection Agency. USEPA. Enforceable Consent Agreement (ECA) and Order for Acetone. (January 1995).

(4) USEPA. ECA and Order for N-Amyl Acetate. (January 1995).

(5) USEPA. ECA and Order for N-Butyl Acetate. (January 1995).

(6) USEPA. ECA and Order for Ethyl Acetate. (January 1995).

(7) USEPA. ECA and Order for Isobutyl Alcohol (January 1995).

(8) USEPA. ECA and Order for Methyl Isobutyl Ketone. (January 1995).

(9) USEPA. ECA and Order for Tetrahydrofuran. (January 1995).

(10) USEPA. ''Economic impact evaluation of proposed multi-chemical rule for the testing of neurotoxicity .'' Economics and Technology Division, OTS, USEPA. Washington, DC. (July 25, 1990).

(11) USEPA. ''Multi-substance rule for the testing of neurotoxicity; proposed rule.'' (56 FR 9105, March 4, 1991).

(12) NIOSH. National Institute for Occupational Safety and Health. National Occupational Exposure Survey (NOES). Computer printout. ((March 29, 1989).

(13) USEPA. ''Household Solvent Products. A National Usage Survey.'' EPA-OTS 560/5–87–005. (July 1987).

(14) Versar, Inc. Springfield, VA. ''Estimates of consumer exposure to ethyl ether''. Memorandum from Carl D'Ruiz, Versar, Inc., to Conrad Flessner, Exposure Assessment Branch, OTS, USEPA.

(15) Syracuse Research Corporation, Syracuse, NY. ''Technical Support for Selection of Solvents for a Neurotoxicity Test Rule.'' Contract No. 68–D8–0117, Task 103. TR 89–218. (January 11, 1990).

(16) USEPA. Toxics-Release Inventory. EPA 560/4–89–006. Office of Pesticides and Toxic Substances, Washington, DC. (June 1989).

(17) USEPA. Minutes of Neurotoxicity Consent Agreement Public Meeting. (July 28, 1994).

(18) USEPA. Proposed addition to SCOB guideline. (September 22, 1994).

VII. Regulatory Assessment Requirements

The Office of Management and Budget (OMB) has approved the information collection requirements contained in the Consent Agreement under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq., and has assigned OMB control 2070–0033.

Public reporting burden for this collection of information is estimated to average 586 hours per response. The estimates include time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

List of Subjects in 40 CFR Part 799

Chemicals, Chemical export, Environmental protection, Hazardous substances, Health effects, Laboratories, Reporting and recordkeeping requirements, Testing.

Dated: January 10, 1995.

Lynn R. Goldman,

Assistant Administrator for Prevention, Pesticides and Toxic Substances.

Therefore, 40 CFR part 799 subpart C is amended as follows:

PART 799—[AMENDED]

1. The authority citation for part 799 continues to read as follows:

Authority: 15 U.S.C. 2603, 2611, 2625.

2. Section 799.5000 is amended by adding acetone, isobutyl alcohol, methyl isobutyl ketone, tetrahydrofuran, *n*-butyl acetate, ethyl acetate, and *n*-amyl acetate to the table in CAS Number order, to read as follows:

§799.5000 Testing consent agreements for substances and mixtures with Chemical Abstract Service Registry Numbers.

* * * * * *

CAS Number	Substance or mixture name	Testing	FR Publication Date
*	*	*	*
67–64–1	Acetone	Health effects	[January 23, 1995]
*	*	*	*
78–83–1	Isobutyl alcohol	Health effects	[January 23, 1995]
*	*	*	*
108–10–1	Methyl isobutyl ketone	Health effects	[January 23, 1995]
109–99–9	Tetrahydrofuran	Health effects	[January 23, 1995]

CAS Number	Substance or mixture name	Testing	FR Publication Date
*	*	*	*
123–86–4	*N*-butyl acetate	Health effects	[January 23, 1995]
*	*	*	*
141–78–6	Ethyl acetate	Health effects	[January 23, 1995]
*	*	*	*
628–63–7	*N*-amyl acetate	Health effects	[January 23, 1995]
*	*	*	*

[FR Doc. 95–1674 Filed 1–20–95; 8:45 am]
BILLING CODE 6560–50–F